REMARKS

In reply to the Office Action dated January 6, 2005, claims 6-11 are currently under examination in the Application. By the above amendment, claim 6 has been amended. Support for the amendment can be found throughout the specification, for example, at page 3, lines 18-20 and page 6, lines 21-22. No new matter has been added. The above amendment is not to be construed as acquiescence to the stated grounds for objection/rejection and is made without prejudice to prosecution of any subject matter modified and/or removed by this amendment in a related divisional, continuation and/or continuation-in-part application.

Rejections under 35 U.S.C. § 102(b)

Claims 6-9 stand rejected as allegedly being anticipated under 35 U.S.C. § 102(b) over PR Newswire (07 December 1998), or Henderson (21 December 1998) as evidenced by U.S. Patent No. 5,858,358. In particular, the Action contends that the references teach that the Xcellerate™ process was used to stimulate an immune response in non-Hodgkin's patients who no longer responded to chemotherapy. The Action further contends that it was well known in the art that chemotherapy patients become immunosuppressed. The Action also opines that the limitation of increasing neutrophil counts is an inherent property of the treatment. Accordingly, the Action concludes that the claimed method is anticipated by the cited references.

Applicant traverses this rejection for the reasons already of record. Applicant notes that independent claim 1 has been amended to recite "wherein said method is not for the treatment of cancer". This amendment is made without acquiescence and without prejudice to prosecution of any subject matter modified and/or removed by this amendment in a related divisional, continuation and/or continuation-in-part application. Applicant submits that the claimed methods were never intended for the treatment of cancer *per se*. However, since the Action is of the view that the method encompasses treatment of cancer, Applicant hereby limits the claims by the negative proviso that the method is not for the treatment of cancer. Applicant submits that it was decided in *In re Johnson* that the use of negative provisos to excise a species disclosed in the prior art from the scope of a claimed genus is permissible. *See*, *In re Johnson*, 558 F.2d 1008, 194 U.S.P.Q. 187 (C.C.P.A. 1977).

Applicant submits that the claims as amended are not anticipated by the cited art and respectfully request withdrawal of the rejection.

Rejections under 35 U.S.C. § 102(f)

Claims 6-11 stand rejected as allegedly being anticipated under 35 U.S.C. § 102(f) because the Applicant did not invent the claimed subject matter. In particular, the Action contends that because it is stated in the PR newswire reference that Xcyte founders Carl June and Craig Thompson "invented a process using monoclonal antibodies attached to beads that bind the CD3 and CD28 receptors to provide costimulatory signals to T cells", that they also must have invented the present invention. Further, the Action alleges that the PR newswire reference in view of U.S. Patent No. 5,858,358 meets the limitations of the claims of treating "artificially induced" immunosuppression and that the limitation of increasing neutrophil counts is merely a description of an inherent property of the treatment itself. Accordingly, the Action concludes that the invention was not invented by the Applicant.

Applicant traverses the rejection and submits that the statements from the Public Relations department of a company have absolutely no bearing to the determination of inventorship, which is a legal determination based on facts. As previously stated, Carl June and Craig Thompson may have invented the anti-CD3 X anti-CD28 beads, a method of using same to activate T cells and to use same for the treatment of cancer. However, nowhere do these inventors even contemplate the present method for treating artificially induced immunosuppression. Applicant reiterates that the present invention is directed not to the treatment of cancer, but to restoring or enhancing immune function in an immunosuppressed individual and, as noted above, the claims have been amended without acquiescence or prejudice, to clarify this. Accordingly, Applicant submits that the claims as amended were invented by Ron Berenson and not by Carl June and Craig Thomson and respectfully requests withdrawal of the rejection.

Rejections under 35 U.S.C. § 103

Claims 10 and 11 stand rejected as allegedly being obvious under 35 U.S.C. § 103(a) over PR Newswire (07 December 1998), or Henderson (21 December 1998) in view of

U.S. Patent No. 5,858,358 and U.S. Patent No. 5,861,406. Claims 1-11 also stand rejected under 35 U.S.C. § 103(a) as allegedly being obvious over U.S. Patent No. 5,858,358 in view of U.S. Patent No. 5,861,406. In particular, the Action contends that one of ordinary skill in the art would have been motivated to use the method described in Newswire and of Henderson for the treatment of any type of immunosuppression, including the well-known immunosuppression due to chemotherapy or radiation treatment (as allegedly taught by the '406 patent) or the use of immunosuppressants, given the teachings of the '358 patent.

Applicant respectfully traverses the rejection for the reasons already of record. Further, Applicant submits that the Action has not established a *prima facie* case of obviousness in that, while it may have been tempting to try to restore or enhance immune function in an artificially induced immuno-compromised or -suppressed individual, there is simply no explicit suggestion in the prior art to do so.

The Examiner cites column 20, lines 33-49 as teaching that the method described therein can be used in therapeutic situations "where it would be desirable to upregulate or enhance an immune response". This blanket statement hardly provides teaching to the skilled artisan of the specific use of the presently claimed methods. In fact, Applicant notes that the lines that follow this citation provide as examples only the well known uses of the method to "enhance a T cell response against tumor-associated antigens." The '358 patent goes on to suggest that "Alternatively, T cells can be stimulated and expanded as described herein to induce or enhance responsiveness to pathogenic agents...". Again, nowhere does the reference teach or suggest the use of such methods for the restoring or enhancing immune function in an artificially induced immuno-compromised or immuno-suppressed subject.

The Action goes on to cite column 10, lines 35-40 of the '406 patent to show that cancer chemotherapy and ionizing radiation was known in the art to be very immunosuppressive. However, there is simply no teaching or suggestion in this reference that the methods described in the '358 patent would be desirable or even effective to restore immune responsiveness in such circumstances. Simply stating that chemotherapy and ionizing radiation can be immunosuppressive is, in itself, insufficient to motivate the skilled artisan to combine the references to arrive at Applicant's invention. On the contrary, the courts have found that explicit

support for motivation to combine references is needed even in art requiring high levels of skill. *In re Rouffet*, 47 USPQ2d 1453, 1458-59, (Fed. Cir. 1998). As discussed in *In re Rouffet*, "...the suggestion to combine requirement stands as a critical safeguard against hindsight analysis and rote application of the legal test for obviousness." (Emphasis added). Thus, Applicant submits that the Action has improperly relied on hindsight to combine the cited references. Accordingly, Applicant respectfully submits that the Action has failed to establish the *prima facie* case of obviousness and requests that the rejection of claims 21 and 22 under 35 U.S.C. § 103(a) be withdrawn.

Rejections under 35 U.S.C. § 112 (New Matter)

Claims 6-11 stand rejected under 35 U.S.C. § 112, first paragraph, as allegedly containing subject matter which is not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the Applicant, at the time the application was filed, had possession of the claimed invention. In particular, the Action contends that the specification as filed fails to reveal support for the generic "artificially induced" immunocomprise or immunosuppression of the claims. The Action alleges that the specification discloses only various primary and secondary causes of immunodeficiency. Accordingly, the Action concludes that the claims recite new matter.

Applicant respectfully traverses this rejection. As an initial matter, Applicant notes that claim 6 has been amended to remove recitation of "wherein said restoring or enhancing immune function comprises an increase in neutrophil counts." Applicant submits that this amendment is made without acquiescence and without prejudice to prosecution of any subject matter removed or modified by this amendment in a related application.

Applicant submits that the courts have held that all that is required to comply with the written description requirement is that the specification **reasonably convey** to persons skilled in the art that the inventor had possession of the subject matter claimed. (*In re Edwards*, 568 F.2d 1349, 1351, 196 USPQ 465, 467 (CCPA 1978) (emphasis added). Applicant submits the specification is not required to describe the claim limitations exactly, "but only so clearly that persons of ordinary skill in the art will recognize from the disclosure that applicants invented

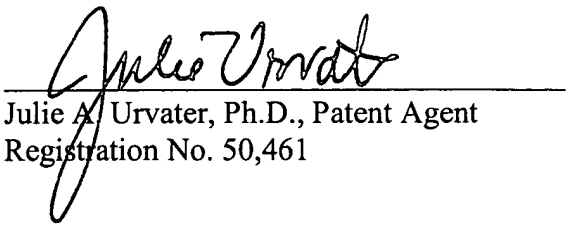
[the subject matter], including those limitations." *In re Wertheim*, 541 F.2d 257, 262; 191 U.S.P.Q. 90, 96 (C.C.P.A. 1976). It is clear from the title of the application alone, "Methods for Restoring or Enhancing T-cell Immune Surveillance Following Naturally or **Artificially Induced Immunosuppression"** that Applicant had possession of the claimed invention at the time of filing. The specification goes on to describe artificially induced immunosuppression in different yet clearly equivalent terms at page 6, lines 19-21: "...secondary immunodeficiencies including those caused by treatment with anti-lymphocyte antibodies (*e.g.*, CAMPATH), chemotherapy, radiation, or immunosuppressant agents..." Applicant submits that the claims "need not be described in *haec verba* to satisfy the description requirement." *In re Smith*, 458 F.2d 1389, 59 C.C.P.A. 1025, 173 U.S.P.Q. 679 (1972). Therefore, Applicant submits that the skilled artisan would understand that Applicant was indeed in possession of the claimed invention and that the term "artificially induced" does not constitute new matter. Reconsideration and withdrawal of the rejection is respectfully requested.

In view of the above amendments and remarks, claims 6-11 are now believed to be in condition for allowance. A good faith effort has been made to place the application in condition for allowance. However, should any further issue require attention prior to allowance, the Examiner is requested to contact the undersigned at 206-622-4900 to resolve same.

The Director is authorized to charge any additional fees due by way of this Amendment, or credit any overpayment, to our Deposit Account No. 19-1090.

Respectfully submitted,

SEED Intellectual Property Law Group PLLC



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